REMARKS

Claims 26-43 are presently pending in the case. In a preliminary amendment filed on July 1, 2003, claims 1-25 were cancelled and claims 26-43 were added.

This application is a continuation of co-pending U.S. Patent Application Serial No. 08/668,036, now US Patent 6,685,967. The presently pending claims are identical to the issued claims in 08/668,036 except that "in the range from 0.1 μm to 5 μm" has been replaced with "below 10 μm".

History of 08/668,036

US Patent Application 08/668,036 (now US Patent 6,685,967), the parent of the present case, was finally rejected by the Examiner. Applicant appealed the final rejections and the rejections were overturned by the Board of Patent Appeals and Interferences. The present claims are identical to the issued claims in 08/668,036 except that "in the range from 0.1 μm to 5 μm" has been replaced with "below 10 μm", as stated above.

The below chart shows the present claims and the issued claims in the parent case and highlights the differences between the claims. The chart also shows the Examiner's rejections of the claims that were overturned by the Board.

Currently pending claims (differences highlighted)	**Issued claims in 08/668,036 (differences highlighted)**	**Rejection in 08/668,036 that was overturned by the Board of Patent Appeals and Interferences**
26. A method for preparing a stable, dry powder insulin composition, said method comprising: dissolving insulin in an aqueous buffer at a concentration in the range from 0.01% to 1% to form a solution; and spray drying the solution to produce substantially amorphous particles having an average size **below 10 μm.**	15 (now 1). A method for preparing a stable, dry powder insulin composition, said method comprising: dissolving insulin in an aqueous buffer at a concentration in the range from 0.01% to 1% to form a solution; and spray drying the solution to produce substantially amorphous particles having an average size **in the range from 0.1 μm to 5 μm.**	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)

27. A method as in claim 26, wherein the insulin is dissolved in a aqueous buffer together with a pharmaceutical carrier, wherein a dry powder having insulin present in individnal particles at from 5% to 99% by weight is produced upon spray drying.	16 (2). A method as in claim 1, wherein the insulin is dissolved in a aqueous buffer together with a pharmaceutical carrier, wherein a dry powder having insulin present in individual particles at from 5% to 99% by weight is produced upon spray drying.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
28. A method as in claim 27, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	17 (3). A method as in claim 2, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
29. A method as in claim 28, wherein the pharmaceutical carrier is a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	18 (4). A method as in claim 3, wherein the pharmaceutical carrier is a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
30. A method as in claim 28, wherein the pharmaceutical carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	19 (5). A method as in claim 3, wherein the pharmaceutical carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696) Further in view of Chien (5,042,975) and/or Markussen (4,946,828)
31. An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size **below 10 μm.**	20 (6). An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size **in the range from 0.1 μm to 5 μm.**	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
32. An insulin composition as in claim 31, wherein the composition is substantially free from penetration enhancers.	21 (7). An insulin composition as in claim 6, wherein the composition is substantially free from penetration enhancers.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)

33. An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	22 (8). An insulin composition as in claim 6, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
34. An insulin composition as in claim 31, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	23 (9). An insulin composition as in claim 6, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696) Further in view of Chien (5,042,975) and/or Markussen (4,946,828)
35. A method for preparing a stable, dry powder insulin composition, said method comprising: providing an aqueous solution of insulin and a pharmaceutical carrier dissolved in an aqueous buffer, wherein the insulin is present at 0.01% to 1% by weight and comprises from 20% to 80% of the total weight of insulin and pharmaceutical carrier in the solution; and spray drying the solution to produce amorphous particles comprising both the insulin and the pharmaceutical carrier having an average size **below 10 μm** and a moisture content below 10%.	26 (10). A method for preparing a stable, dry powder insulin composition, said method comprising: providing an aqueous solution of insulin and a pharmaceutical carrier dissolved in an aqueous buffer, wherein the insulin is present at 0.01% to 1% by weight and comprises from 20% to 80% of the total weight of insulin and pharmaceutical carrier in the solution; and spray drying the solution to produce amorphous particles comprising both the insulin and the pharmaceutical carrier having an average size **in the range from 0.1 μm to 5 μm** and a moisture content below 10%.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
36. A method as in claim 35, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	27 (11). A method as in claim 10, wherein the pharmaceutical carrier is a carbohydrate, organic salt, amino acid, peptide, or protein which produces a powder upon spray drying.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)

37. A method as in claim 36, wherein the carbohydrate carrier is selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	28 (12). A method as in claim 11, wherein the carbohydrate carrier is selected from the group consisting of mannitol, raffinose, lactose, malto dextrin and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
38. A method as in claim 36, wherein the carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	29 (13). A method as in claim 11, wherein the carrier is an organic salt selected from the group consisting of sodium citrate, sodium acetate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
39. (Previously presented) An insulin composition for pulmonary delivery, said composition comprising: a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size **below 10 μm**, and have a moisture content below 10%.	30 (14). An insulin composition for pulmonary delivery, said composition comprising: a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight, have an average particle size **in the range from 0.1 μm to 5 μm**, and have a moisture content below 10%.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
40. An insulin composition as in claim 39, wherein the particles consist essentially of the insulin and the pharmaceutical carrier.	31 (15). An insulin composition as in claim 14, wherein the particles consist essentially of the insulin and the pharmaceutical carrier.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
41. An insulin composition as in claim 39, wherein the composition is substantially free from penetration enhancers.	32 (16). An insulin composition as in claim 14, wherein the composition is substantially free from penetration enhancers.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)
42. An insulin composition as in claim 39, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	33 (17). An insulin composition as in claim 14, wherein the pharmaceutical carrier material comprises a carbohydrate selected from the group consisting of mannitol, raffinose, lactose, malto dextrin, and trehalose.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696)

43. An insulin composition as in claim 39, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	34 (18). An insulin composition as in claim 14, wherein the pharmaceutical carrier material comprises an organic salt selected from the group consisting of sodium citrate, sodium gluconate, and sodium ascorbate.	35 USC 103(a) Platz (5,354,562) and AKZO (EP 0 360 340) in view of Manier (5,482,927) Okada (4,211,769) Hirai (4,659,696) Further in view of Chien (5,042,975) and/or Markussen (4,946,828)

A copy of the Board's decision has been included for the Examiner's convenience.

Current rejections

The Examiner rejected claims 1-25 under 35 USC 102(b) and/or under 35 USC 103(a) as being anticipated by or as being obvious over one or more of AZKO (EO 0 360 340), Patton et al (WO 93/00951), Rubsamen (5,364,838), Chien (US 5,042,975), Markussen (US 4,946,828), JP 56 138 110, Manier (US 5,482,927), Okada (4,211,769), and Hirai (US 4,659,696).

Each of claims 1-25 were cancelled in the preliminary amendment of July 1, 2003. Accordingly, the rejection of the claims is believed to be moot. Furthermore, the rejections are not believed to be proper in that the teachings of the references was considered by the Board of Patent Appeals and Interferences and the claims of 08/668,036 were found to be allowable thereover. Note that Patton et al (WO 93/00951) corresponds to US Patent 5,458,135.

Claim rejections under judicially created doctrine of Double Patenting

The Examiner rejected claims 1-24 under the judicially created doctrine of double patenting as being unpatentable over various patents and patent applications. Again, the rejections are believed to be moot since claims 1-24 were previously cancelled. Applicant will submit a terminal disclaimer in compliance with 37 CFR 1.321(c) to overcome any double patenting rejections, where appropriate, upon the indication of allowable subject matter.

Information Disclosure Statement

Applicant filed an information disclosure statement on November 8, 2004. Indication of consideration of the references cited therein is requested. In addition, Applicant is filing under separate cover a supplemental information disclosure statement in compliance with MPEP section 609. Indication of consideration of the references provided is requested.

Conclusion

The Examiner is respectfully requested to consider the presently pending claims. Should the Examiner have any questions, the Examiner is requested to call the undersigned at the number given below.

Respectfully submitted,

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Dated: 21 APR 2005

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Paper No. 43

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN R. PATTON,
LINDA FOSTER, and
ROBERT M. PLATZ

Appeal No. 2002-1128
Application No. 08/668,036

HEARD: January 9, 2003

Before WINTERS, MILLS, and GREEN, Administrative Patent Judges.

WINTERS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 15 through 24 and 26 through 34, which are all of the claims remaining in the application.

The Invention

The invention relates generally to methods and compositions for the respiratory delivery of insulin to diabetic patients. More particularly, the invention relates to the

pulmonary delivery of dry powder insulin preparations for rapid systemic absorption through the lungs. Claims 15, 20, and 24, which are illustrative of the subject matter on appeal, read as follows:

15. A method for preparing a stable, dry powder insulin composition, said method comprising:

dissolving insulin in an aqueous buffer at a concentration in the range from 0.01% to 1% to form a solution; and

spray drying the solution to produce substantially amorphous particles having an average size in the range from 0.1 μm to 5 μm.

24. An insulin composition produced by the method of claim 15.

20. An insulin composition for pulmonary delivery, said composition comprising a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material, wherein the particles have an average size in the range from 0.1 μm to 5 μm.

The Prior Art References

In rejecting the appealed claims under 35 U.S.C. § 103(a), the examiner relies on the following prior art references:

Okada et al. (Okada)	4,211,769	Jul. 8, 1980
Hirai et al. (Hirai)	4,659,696	Apr. 21, 1987
Markussen	4,946,828	Aug. 7, 1990
Chien et al. (Chien)	5,042,975	Aug. 27, 1991
Platz et al. (Platz)	5,354,562	Oct. 11, 1994
Maniar et al. (Maniar)	5,482,927	Jan. 9, 1996
AKZO (European Patent Appln.)	EP 0 360 340	Mar. 28, 1990

The Rejections

Claims 15 through 24 and 26 through 34 stand rejected under 35 U.S.C. § 103(a) "as being unpatentable over Platz (5,354,562) and EP 0 360 340 (AZCO) [sic] of record by themselves or in combination, further in view of Maniar (5,482,927), Okada (4,211,769), Hirai (4,659,696) by themselves or in combination." (Examiner's Answer, page 3).

Claims 19, 23, and 34 further stand rejected under 35 U.S.C. § 103(a) "as being unpatentable over Platz and EP by themselves or in combination, in view of Maniar (5,482,927), Okada (4,211,769), Hirai (4,659,696) by themselves or in combination as set forth above, further in view of Chien (5,042,975) and/or Markussen (4,946,828)." (Examiner's Answer, page 6).

Deliberations

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1 through 9 and all of the claims on appeal; (2) applicants' Appeal Brief (Paper No. 27); (3) the Examiner's Answer (Paper No. 28); and (4) the above-cited prior art references.

On consideration of the record, including the above-listed materials, we reverse the examiner's prior art rejections. On return of this application to the examining corps, we recommend that the examiner reevaluate the patentability of product-by-process claim 24 in light of the ensuing discussion.

Discussion

Independent claim 15 requires spray drying an aqueous solution of insulin "to produce substantially amorphous particles having an average size in the range from 0.1 μm to 5 μm." Likewise, independent claim 26 requires spray drying an aqueous solution of insulin and a pharmaceutical carrier "to produce amorphous particles comprising both the insulin and the pharmaceutical carrier having an average size in the range from 0.1 μm to 5 μm." We agree with applicants' argument (Appeal Brief, pages 10 and 11) that the cited prior art is insufficient to support a conclusion of obviousness of claims containing those limitations. Nor has the examiner adequately come to grips with those specific claim limitations.

Independent claim 20 calls for an insulin composition for pulmonary delivery, said composition comprising "a dry powder of individual particles which include insulin present at from 20% to 80% by weight in a pharmaceutical carrier material." Again, the insulin composition recited in claim 30 comprises "a dry powder of individual amorphous particles including both insulin and a pharmaceutical carrier, wherein the particles comprise from 20% to 80% insulin by weight." We agree with applicants (Appeal Brief, page 13) that the cited prior art is insufficient to support a conclusion of obviousness of claims containing those limitations. Nor has the examiner adequately come to grips with those specific claim limitations.

Furthermore, in rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. 37 CFR § 1.104(c)(2).

Here, the examiner issued what could only be described as a "shotgun" rejection of claims 15 through 24 and 26 through 34 under 35 U.S.C. § 103(a) as unpatentable over Platz and AKZO "of record by themselves or in combination," further in view of Maniar, Okada [and] Hirai "by themselves or in combination." The examiner separately rejected claims 19, 23, and 34 under 35 U.S.C. § 103(a) over that same combination of references, further in view of Chien "and/or" Markussen. By formatting rejections in this manner, the examiner obfuscated rather than clarified the issues on appeal and we would be constrained to reverse on procedural grounds alone. Cf. In re Herrick, 344 F.2d 713, 716, 145 USPQ 400, 401 (CCPA 1965) (Because of indefinite statement of the grounds of rejection, "the existing situation does not permit rational isolation and determination of the legal issues which may be present.") Accord, Ex parte Blanc, 13 USPQ2d 1383 (Bd. Pat. App. & Int. 1989).

On return of this application to the examining corps, we recommend that the examiner reevaluate the patentability of product-by-process claim 24. This claim is drawn is drawn to an insulin composition "produced by the method of claim 15."

As stated in In re Thorpe, 777 F.2d 695, 697, 227 USPQ 964, 966 (Fed. Cir. 1985):

> [E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. . . . The patentability of a product does not depend on its method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. [Citations omitted.]

Further, in discussing product-by-process claims in In re Brown, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972), the court stated:

> [I]n spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. [Emphasis added.]

Applying those principles of law to the facts before us, we believe that Platz discloses a product "which reasonably appears to be either identical with or only slightly different than" the product recited in claim 24.

Generally speaking, the Platz disclosure relates to inhalation therapy involving the administration of a drug in aerosol form to the respiratory tract. According to Platz, "the present invention is useful for transforming polypeptide drugs into a powder form that is suitable for aerosol administration" (column 2, lines 13 through 15). Examples of such polypeptides include, inter alia, insulin (column 2, line 21). Platz discloses a two-step process where "[t]he first step in the process for forming the polypeptides into micronized particles is lyophilization" (column 2, lines 38 through 40). Subsequently, the lyophilized polypeptide is size reduced in a grinding mill, preferably a fluid energy mill also known as a jet mill (column 3, lines 3 through 5). The particle size of the milled powder disclosed by Platz appears to be essentially the same as the particle size

recited in claim 15 from which claim 24 depends (Platz, column 3, line 65 through column 4, line 19).

On this record, it would appear that Platz discloses a stable, dry powder insulin composition containing substantially amorphous particles having a particle size essentially the same as the particle size recited in claim 15. Even though the composition of claim 24 is "produced by the method of claim 15" which requires spray drying an aqueous solution of insulin, nevertheless, the product of claim 24 "reasonably appears to be identical with or only slightly different than" the product disclosed by Platz. In this regard, we invite attention to the following description in applicants' specification, page 9, lines 20 through 31:

> Insulin dry powders suitable for use in the present invention include amorphous insulins, crystalline insulins, and mixtures of both amorphous and crystalline insulins. Dry powder insulins are preferably prepared by spray drying under conditions which result in a substantially amorphous powder having a particle size within the above-stated range. Alternatively, amorphous insulins could be prepared by lyophilization (freeze-drying), vacuum drying, or evaporative drying of a suitable insulin solution under conditions to produce the amorphous structure. The amorphous insulin so produced can then be ground or milled to produce particles within the desired size range. [Emphasis added].

We recommend that the examiner (1) take a hard look at claim 24 in light of the foregoing discussion and relevant case law; and (2) determine whether to enter a rejection of claim 24 over Platz, based alternatively on 35 U.S.C. § 102 or 35 U.S.C. § 103(a).

Conclusion

In conclusion, for the reasons set forth in the body of this opinion, we reverse the examiner's rejections of the appealed claims under 35 U.S.C. § 103(a). On return of this application to the examining corps, we recommend that the examiner reevaluate the patentability of product-by-process claim 24.

REVERSED

Sherman D. Winters
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Lora M. Green
Administrative Patent Judge

) BOARD OF PATENT APPEALS AND INTERFERENCES

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